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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,396	12/18/2001	Kenneth W. Dobie	RTS-0339	5833

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,396	DOBIE, KENNETH W.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed July 24, 2003 and November 4, 2003 have been considered. Rejections and/or objections not reiterated from the previous office action mailed March 27, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 24, 2003 has been entered.

Response to Traversal of Election/Restrictions

Applicant's election with traverse of antisense compounds targeted to CD36L1 of SEQ ID NO: 3 in the paper filed November 4, 2003 is acknowledged. The traversal is on the ground(s) that "by definition, the sequences cannot be independent because they all target and modulate the same single sequence namely SEQ ID NO: 3". Applicants assert that because there is a disclosed and acknowledged relationship between the sequences, that restriction to one

sequence is thus improper. This is not found persuasive because while each antisense oligo sequence may be related to a common target sequence, the individual antisense sequences are not otherwise related to each other. The fact that the antisense sequences encompassed by claim 1 are related to the same target does not confer upon them a common core structure that is shared between the actual antisense sequences themselves. To the contrary, the antisense sequences encompassed in applicants' claim 1 are structurally and functionally independent and distinct because each antisense sequence necessarily has a unique nucleotide sequence, each targets a different and specific region of the molecule encoding SEQ ID NO: 3, and each sequence, upon binding to the molecule encoding CD36L1, functionally modulates the expression of the gene to varying degree (as evidenced in Table 1 of the specification).

Furthermore, applicants assertion that there is no added search burden in searching multiple individual regions of SEQ ID NO: 3 because a search against the breadth of SEQ ID NO: 3 would reveal all art against that target is not considered convincing. The search for oligos against the broad target of SEQ ID NO: 3 is not considered to be an exhaustive, all-revealing search for any oligo that may be complementary to the target. Such a search would potentially yield a staggering and unwieldy number of hits that are complementary and are between 8 and 50 nucleotides long. Out of necessity, the search is designed to return a manageable number of good results, such that the Office is able to cite the best art against applicants' broad claim 1 as required by 37 CFR 1.104(c). Furthermore, applicant's amendment to recite distinct regions off the target serves essentially to claim distinct sequences, since each must be searched separately as claimed, and, since each region is a unique sequence. Accordingly, the search of multiple

sequences is considered to be a search burden, and the requirement is still deemed proper and is therefore made FINAL.

The subject matter of claim 1 drawn to target regions of SEQ ID NO: 3 other than nucleobases 169 through 1594 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed November 4, 2003.

Response to Arguments

Claims 1, 2, 4-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acton et al. (U.S. Patent Number 5,965,790), in view Calvo et al. and Baracchini et al. (U.S. Patent Number 5,801,154). These references are of record from the first Office action on the merits mailed June 5, 2002, and is repeated for the same reasons of record as cited in the Office action mailed March 27, 2003. Arguments from applicants' response entered July 24, 2003 that are considered relevant to the instant rejection are addressed below.

Applicants have amended the instant claims, such that they are now drawn to antisense oligos targeted to specific regions of the CD36L1 target of SEQ ID NO: 3, said regions identified by nucleobase. The amended claims were previously made subject to a restriction requirement, and applicants elected to prosecute the region of the target corresponding to nucleobases 169 to 1594 of SEQ ID NO: 3.

A review of Table 1 of the specification indicates that this region corresponds to the entire coding region of SEQ ID NO: 3. Therefore, applicants have essentially elected the coding

region of SEQ ID NO: 3. Furthermore, it was set forth in the instant obviousness rejection that it would be obvious to one of ordinary skill in the art to target the coding region, because Baracchini et al. indicate that this region is a preferred region for targeting a transcript using antisense mediated inhibition, as evidenced by the following passage discussing preferred regions of targeting: "The open reading frame (ORF) or "coding region", which is known in the art to refer to the region between the translation initiation codon and the translation termination codon, is also a region which may be targeted effectively." Accordingly, applicants' amendment electing the coding region of SEQ ID NO: 3 is not considered to free the claim from the prior art, because one of ordinary skill would have understood from the prior art that the coding region is an effective region for targeting.

Applicants also argue that, when viewed alone, none of Acton et al., Calvo et al. or Baracchini et al. teach or suggest antisense compounds targeted to the specific regions of the CD36L1 transcript of SEQ ID NO: 3 as presently claimed. This argument is not adopted, because the presently claimed compounds are still considered to fall within the ambit of the cited art as discussed above. Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is acknowledged that the references when viewed individually do not teach the presently claimed invention; however, the test for obviousness is what the *combined* teaching of the prior art would have suggested to those of ordinary skill in the art. As indicated above, one of ordinary skill in the art would have been motivated to make antisense oligonucleotides based on Acton's teaching

of antisense targeted to applicants claimed target. Moreover, Baracchini et al. teaches all the steps required for synthesizing and using antisense oligos to inhibit a transcript of known sequence. Baracchini teaches the requisite level of detail required to achieve such inhibition, such as starting reagents, synthesis protocols, incubation times and conditions, and finally, assays for determining which compounds attain the highest levels of inhibition. Finally, these because these steps are considered routine to one of ordinary skill in the art, this combination of references also provides a reasonable expectation of success which render the invention of the claims above obvious under 35 U.S.C. § 103(a).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 103 that form the basis for the rejections under these sections made in this Office action:

> A person shall be entitled to a patent unless –
>
> 102(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> 103(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 12, and 14 are rejected under 35 U.S.C. 102(e) and 103(a) as being anticipated and/or obvious by Fielding (U. S. Patent Number 6,261,760 B1).

The claims of the above invention are drawn to antisense compounds 8 to 50 nucleotides in length that specifically hybridizes with and inhibits the expression of CD36L1 SEQ ID NO: 3.

SEQ ID NO: 7 et al. possesses 100% identity with residues 1514 to 1543 of SEQ ID NO: 3 of the instant application, and would thus specifically hybridize with applicants claimed target. Although this reference does not specifically teach the function of inhibiting applicants' instant SEQ ID NO: 3 as claimed in the present application, the above-listed compound meets all the structural limitations as set forth in the instant claims. Because the compound is substantially identical to applicant's claimed compound, in the absence of evidence to the contrary the compound of Fielding is thus considered to possess the functional limitation of specifically hybridizing with and inhibiting the expression of applicants' instant SEQ ID NO: 3. Support for this conclusion is drawn from MPEP 2112:

> Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.** "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. 102 and 103, a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound(s) of the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or

> obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Thus, in the absence of evidence to the contrary, the antisense compounds of claims 1, 2, 12, and 14 of the instant application are considered anticipated and/or obvious as outlined above.

Claims 1, 2, 12, and 14 are rejected under 35 U.S.C. 102(e) and 103(a) as being anticipated and/or obvious by Zhang et al. (WO 02/34883 A2).

The claims are drawn to the invention as described above.

SEQ ID NO: 22 of Zhang et al. possesses 100% identity with residues 1120-1147 of SEQ ID NO: 3 of the instant application, would thus specifically hybridize with applicants claimed target, and is presumed to inhibit applicants' target for the same reasons as described above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JDS
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SEAN McGARRY
PRIMARY EXAMINER
1635